

## 5. 510(K) SUMMARY OR 510(K) STATEMENT

This summary of 510(k)-safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Date Prepared: March 5, 2007

APR - 6 2007

510(k) number: 070803

### Applicant Information:

Anatomage Inc.  
111 N. Market Street #930  
San Jose, CA 95113

### Contact Person

Robert J. Chin Ph.D.  
Phone Number: (650) 593-5225

### Device Information:

Trade Name: *InVivoDental*™  
Classification: Class II  
Classification Name: Imaging Processing System

### Physical Description:

*InVivoDental* is a volumetric imaging software designed specifically for dental clinicians. The software reads DICOM data from dental CT machines including I-CAT, NewTom, MecuRay and Accutomo. The software runs in Windows XP operating system and visualizes the DICOM data on the computer screen. The software is downloaded over the internet and installed on the customer's computer.

### Intended Use:

*InVivoDental* is intended for use as a front-end software interface for the transfer of imaging information from a medical scanner such as a Dental CT scanner. It is also intended for use as a planning and simulation software in the placement of dental implants, orthodontics and surgical treatment

### Equivalent Device:

The subject device is substantially equivalent in intended use and/or method of operation to the Materialise N. V. SimPlant System (K033849, K053592), Cybermed Vimplant (K053155) And Implant Logic VIP System (K060267)

### Test Results:

#### Performance

Results of in-vitro testing demonstrate that the *InVivoDental* is safe and effective for its intended use.

**Summary:**

Based on the intended use, product, performance and software information provided in this notification, the subject device has been shown to be substantially equivalent to the currently marketed predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
9200 Corporate Blvd.  
Rockville MD 20850

Anatomage, Inc.  
c/o Mr. Morten Simon Christensen  
Staff Engineer & FDA Office Coordinator  
Underwriters Laboratories, Inc.  
455 East Trimble Road  
SAN JOSE CA 95131

APR - 6 2007

Re: K070803  
Trade/Device Name: *InVivoDental™*  
Regulation Number: 21 CFR §892.2050  
Regulation Name: Picture archiving and communications system  
Regulatory Class: II  
Product Code: LLZ  
Dated: March 22, 2007  
Received: March 23, 2007

Dear Mr. Christensen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.



*Protecting and Promoting Public Health*

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

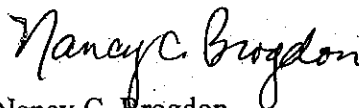
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>

Sincerely yours,



Nancy C. Brogdon  
Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

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#### 4. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K070803Device Name: InVivoDental

## Indications for Use:

*InVivoDental* is intended for use as a front-end software interface for the transfer of imaging information from a medical scanner such as a CT scanner. It is also intended for use as a planning and simulation software in the placement of dental implants, orthodontics and surgical treatment

Prescription Use ☒  
(Part 21 CFR 801 Subpart D)

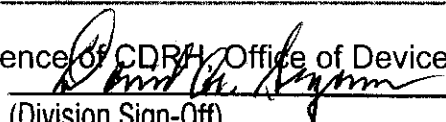
AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE  
OF NEEDED)

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Concurrence of CDRH Office of Device Evaluation (ODE)

  
(Division Sign-Off)

Division of Reproductive, Abdominal, and  
Radiological Devices

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